REMARKS

Reconsideration is requested.

Claims 1-59 have been canceled, without prejudice.

Claims 60-86 have been added and are pending. No new matter has been added.

The Section 102 rejection of claims 25-27, 33, 37-46 and 50-51 over Cha (WO 92/19743), is moot in view of the above. The Section 103 rejection of claims 52-57 over Cha in view of the Stratagene Catalog (1988), is moot in view of the above.

The assignee believes that new claims 60-86, better define embodiments of applicants' invention and take into account the construction of the term "method of genotyping" as found by the Court in the Abbott litigation (discussed below) and as previously discussed by the Patent Office in allowing applicants' earlier U.S. Patent 5,846,704 ("the '704 patent").

The assignee submits that claims 85 and 86 are substantially similar to previously allowed claims 58 and 59.

Initially, the assignee notes that an Information Disclosure Statement ("the IDS") is being prepared to make of record documents that the assignee believes to be relevant from their pending litigation with Abbott Laboratories Inc. ("Abbott"), and concluded litigation with Third Wave Technologies Inc. ("TWT") in the District Court for the Western District of Wisconsin involving the '704 patent. A summary of litigation events which the assignee believes to be relevant in both the TWT and Abbott litigations is also being prepared to be provided with the IDS.

The Examiner has previously considered the "Expert Report of Bruce K. Patterson, M.D. Regarding the invalidity of Innogenetics, N.V.'s U.S. Patent No. 5,846,704", signed April 10, 2006 (33 pages with 14 page Exhibit A Curriculum Vitae, 2 page Exhibit B, 2 page Exhibit C, 2 page Exhibit D). The Examiner has referenced same in the Office Action of July 27, 2006. Since issuance of the Office Action of July 7, 2006, the assignee notes that the Court in the Abbott litigation issued (on August 3, 2006), an Order denying a motion brought by Abbott for summary judgment of invalidity of the '704 patent on grounds of anticipation and obviousness.

Thereafter, beginning August 28, 2006, the assignee notes that a jury trial was held between Innogenetics and Abbott in the District Court for the Western District of Wisconsin. In the first part of the trial, the assignee notes that a jury was asked to determine whether the Cha PCT application anticipated the claims of the '704 patent. During the trial, the assignee submits that Dr. Patterson expressed the opinion provided in his expert report that the '704 patent was anticipated by the Cha PCT application. The assignee further submits that jury also heard the testimony of Innogenetics' expert witnesses, Drs. Worman and Reznikoff, who opined that the Cha PCT did not anticipate the '704 patent. The assignee further submits that the jury also heard other witnesses presented by the parties, and after being instructed by the Court on the construction of the claims and applicable law, the jury returned a verdict that the Cha PCT did not anticipate the claims of the '704 patent.

Following the jury verdict of no anticipation over the Cha PCT, the assignee notes that Abbott again asserted invalidity of the '704 patent claims in post-trial motions. The assignee further notes that Abbott's arguments of invalidity were again rejected by the Court in its Order rendered January 3, 2007.

The assignee notes that Drs. Worman and Reznikoff explained in their expert reports and at trial that persons of skill in the art would not have read the Cha PCT to teach the use of probes to genotype, i.e., to distinguish and classify HCV, but rather only to detect. As the assignee believes they explained, and as found by the Court in its claim construction – and indeed as found by the Examiners of the '704 patent – applicants method genotyping requires both distinguishing and classifying, and is different than just merely detecting. In this regard, the assignee notes that the Notice of Allowability of the '704 patent, dated November 4, 1997, stated in part:

> * * * The claims are allowable over the prior art because the instant methods are concerned with "genotyping" HCV rather than just "detecting" HCV. Although genotyping falls under the umbrella of detecting, it is a specific and selective type of detection whereby different genotypes of similar virus strains can be distinguished. Mere detection methods permit detection of numerous types and subtypes of HCV without distinguishing among them. Hence, the term "method of genotyping" means distinguishing among HCV types and/or subtypes...

The assignee believes that the foregoing arguments are even further true as they pertain to the instant claims, which require the probes to distinguish and classify from at least three up to six genotypes of HCV selected from the group consisting of HCV types 1-6, if present in the sample. More specifically, new claims 60-85 recite methods of

genotyping HCV nucleic acids present in a biological sample comprising the steps of (1) contacting nucleic acids of the 5' UTR of HCV in a biological sample with multiple oligonucleotide probes under reaction conditions in which the probes specifically hybridize to target sequences in said HCV 5' UTR nucleic acids within the region extending from the nucleotides at positions -291 to -66, if present in the biological sample, and (2) determining whether one or more of the probes have hybridized to said nucleic acids of HCV. Consistent with the Court's claim construction, the assignee believes that the claims further specify that, under the reaction conditions, the probes specifically hybridize (i.e., hybridize to target sequences and not to non-target sequences) to target sequences in the 5' UTR and thus can both distinguish among various subtypes and classify the sample into the correct genotype.

In addition to the art of record, the Examiner is respectfully requested to review the documents provided in the IDS. The assignee believes that among the more-pertinent documents relating to the validity of the '704 patent claims are the Patterson, Worman and Reznikoff expert reports relating to Abbott's arguments of invalidity, the trial transcripts of the testimony of Drs. Patterson, Worman and Reznikoff (see especially days August 29-31, 2006), as well as the other witnesses, the parties' summary judgment briefing, their post-trial briefing, the Court's August 3, 2006 Order relating to Abbott's motion for summary judgment of invalidity and the Court's recent January 3, 2007 post-trial Order related to Abbott's post-trial arguments of invalidity.

For the reasons fully explicated in those documents, the assignee respectfully submits that the claims are patentable over the art of record. The assignee submits that neither the Cha PCT nor the Cha US '693 patent would be deemed by a person of

ordinary skill in the art to have disclosed a method of genotyping in which probes could distinguish and classify the genotype of HCV as claimed in the claims of the '704 patent. The assignee believes this is because a method of genotyping requires more than merely detecting HCV genotypes as is disclosed in the Cha PCT and Cha US '693 patent -- it requires that the probes be able to distinguish among different genotypes of HCV and classify the HCV into the correct genotype.

In this regard, the assignee submits that Figure 4e of the Cha PCT, for example, discloses sequences that are merely the 12 tail end nucleotides of the 252 nucleotide sequences begun at nucleotide 1 on Figure 4a. The Examiner will thus appreciate that these are not probe sequences, nor is there any suggestion that these sequences or some unidentified (by Cha et al.) fragment of them would be capable of specifically hybridizing to target sequences in the 5' UTR (much less what those target sequences are), or that they would have any hope of distinguishing among sequences of other HCV genotypes or be finally able to classify the HCV based on specific hybridization to genotype-specific target sequences. (On this point, the assignee requests the Examiner to see the transcript of Dr. Worman's testimony of the August 30, 2006 10:10 a.m. session beginning at page 4.) The assignee further wishes to draw the Examiner's attention to the fact noted in the Worman Expert Report that Cha et al. in fact were wrong in their classification of HCV genotype II. The assignee believes that the applicants realized that Cha's Genotype II was in fact not a separate genotype but rather a subtype of Genotype 1 – a recognition which ultimately was agreed upon by the HCV community and which had a significant impact in terms of understand how to actually design a 5' UTR probe-based test for genotyping.

As noted above, and as the assignee believes is consistent with that notion and the Court's construction of the phrase "method of genotyping" in the Abbott litigation, the new claims of this application have been drafted to specify that the probes are used under reaction conditions in which they are able to specifically hybridize and both distinguish among genotypes having similar sequences and correctly classify genotype. Accordingly, just as the assignee believes the judge and jury in the Abbott litigation concluded, Cha et al. did not disclose to skilled artisans the method of genotyping HCV using specifically hybridizing probes claimed in the '704 patent claims, and thus there is also no anticipation of prior pending claims 25-59 or of the new claims 60-86.

The claims are submitted to be patentable over the art of record. In the event the Examiner maintains any art rejection based on Cha, the Examiner is requested to identify where the reference teaches and/or suggests a method of genotyping in which probes were used to specifically hybridize to the 5' UTR of HCV in a manner that would have permitted an ordinarily skilled person to distinguish and classify at least three genotypes of HCV. The assignee further submits that the cited Stratagene kit fails to remedy the deficiencies of the primary reference.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required in this regard.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /B. J. Sadoff/
B. J. Sadoff
Reg. No. 36,663

BJS:
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100